

**REMARKS**

Favorable reconsideration of this application is respectfully requested in view of the foregoing amendments and following remarks. Applicants have amended claims 1, 2 and 30.

Claims 1, 2, 5-7 and 9-14 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,911,711 to Pelkey. This rejection is traversed. Nowhere does Pelkey disclose a method for manufacturing a siliconized surgical needle by “applying a coating mixture on the surface of the needle, the coating mixture comprising at least one polydialkylsiloxane having a molecular weight sufficient to provide a viscosity of the coating mixture of at least about 10,000 cp and at least one other siliconization material; and, curing the coating mixture on the surface of the needle to provide a silicone coating thereon” as required by applicants’ amended claim 1.

Rather, Pelkey discloses coating a hypodermic needle with multiple coatings. Pelkey describes his coatings in the summary of invention as follows: “The lubricious coating has a first layer formed from an at least partially cured organosiloxane copolymer and polydimethylsiloxane that has a viscosity greater than about 1000 centistokes. The lubricious coating has a second layer, applied as a secondary operation onto the first layer, that includes a polydimethylsiloxane having a viscosity between about 50 centistokes and about 350 centistokes.” Pelkey goes on to describe his first coating as including “about four parts of a mixture of {50% solids (w/w)} dimethyl cyclosiloxane and dimethoxysilyldimethylaminopropyl silicone polymer in a mixture of mineral spirits and isopropyl alcohol (available from Dow-Corning, Midland, MI, as MDX 4-4159 fluid)

and about two parts of polydimethylsiloxane (12,500 centistoke viscosity, available as DC-360 from Dow-Coming, Midland, Mich.).” (See Pelkey at column 3, lines 11-17.)

As set forth in the Material Safety Data Sheet for MDX4-4159 (a copy of which is attached hereto as Exhibit A), MDX4-4159 has a viscosity of 160 centistokes. It is respectfully submitted that there is no evidence in Pelkey that its mixture of 4 parts of MDX4-4159, having a viscosity of only 160 centistokes, in combination with 2 parts of a polydimethylsiloxane having a viscosity of 12,500 would, in fact, inherently possess a viscosity of more than about 10,000 cP, especially in view of the fact that the summary of invention describes “a first layer formed from an at least partially cured organosiloxane copolymer and polydimethylsiloxane that has a viscosity greater than about 1000 centistokes.”

Moreover, as noted in applicant’s specification, its preferred polydimethylsiloxanes have “a molecular weight sufficient to provide a viscosity of the coating mixture of at least about 10,000 cp and preferably of at least about 30,000 cp. Such polydimethylsiloxanes for use herein include the products sold by Dow Corning under the name “Syl-Off DC 23”, which is suitable as a high density condensable polydimethylsiloxane, and NuSil Technology under the name “MED1-4162 (30,000cp).” (See Specification at page 6, lines 1-5.)

Thus, there is nothing in Pelkey to demonstrate Pelkey’s first coating would, in fact, have a viscosity of more than 10,000 cP as taught in Claim 1. The Office Action’s reliance upon applicant’s recitation of polydimethylsiloxane in a dependent claim as

material which could be used in applicant's composition to reject the independent claims is thus improper.

Moreover, nowhere does Pelkey disclose or suggest that its coating may be utilized for surgical needles. The Examiner asserts the needles of Pelkey *could* be used during the course of surgery; however this argument fails to appreciate the difference between the use of a hypodermic needle, which is used either a single time or a very few times (e.g., for the administration of a local anesthetic) and thus has limited penetration in a patient, and the use of a surgical needle, which may be passed through a patient's tissue numerous times to adequately close a wound.

With respect to applicant's curing steps, the Office Action fails to recognize the difference between the multiple coatings of Pelkey and applicants' single coating mixture. The Office Action describes in detail the different cure steps for Pelkey's different coatings, not recognizing the cure steps carried out by applicants are for a single, mixed coating. Not only does Pelkey fail to disclose the use of a single coating, nowhere in Pelkey is there any teaching or suggestion to cure the compositions on its needles by "subjecting the coating mixture to an atmosphere of from about 20% to about 80% relative humidity, at a temperature from about 10° C. to about 50° C. for a time period ranging from about 1 hour to about 6 hours; and, heating the coating mixture to a temperature of from about 100° C. to about 200° C. for a time period ranging from about 2 hours to about 48 hours" as required by claims 10 and 11.

Similarly, there is no teaching or suggestion in Pelkey to cure the compositions on its needles by "subjecting the coating mixture to an atmosphere of from about 50% to

about 65% relative humidity, at a temperature from about 20° C. to about 35° C. for a time period ranging from about 2 hours to about 4 hours; and, heating the coating mixture to a temperature of from about 115° C. to about 150° C. for a time period ranging from about 15 hours to about 25 hours” as required by claims 12 and 13.

While the Office Action suggests one skilled in the art would have known the temperature and time to cure these materials, there is no support for this assertion. Pelkey’s “curing” steps are for the two different coatings; applicants’ curing steps are applied to the single coating mixture. Thus, there is no teaching or suggestion in Pelkey for the parameters found in Applicants’ multiple stage curing process for the single mixture. In view of the foregoing, withdrawal of the rejection of claims 1, 5-7 and 9-14 is respectfully requested.

Claims 3-4, 8 and 15 have been rejected under 35 U.S.C. §103(a) as obvious over Pelkey in view of U.S. Patent No. 5,456,948 to Mathisen et al. This rejection is traversed. Nowhere does Mathisen disclose a method for manufacturing a siliconized surgical needle by “applying a coating mixture on the surface of the needle, the coating mixture comprising at least one polydialkylsiloxane having a molecular weight sufficient to provide a viscosity of the coating mixture of at least about 10,000 cp and at least one other siliconization material; and, curing the coating mixture on the surface of the needle to provide a silicone coating thereon” as required by applicants’ amended claim 1.

Without remedying the deficiencies of Pelkey noted above, Mathisen cannot be utilized to render claims 3-4, 8 and 15 obvious.

Claims 1-2, 9 and 30 have been rejected under 35 U.S.C. §103(a) as obvious over Prasad EP 627474. This rejection is traversed. Nowhere does Prasad disclose or suggest applying a coating mixture on the surface of the needle, the coating mixture comprising at least one polydialkylsiloxane having a molecular weight sufficient to provide a viscosity of the coating mixture of at least about 10,000 cp and at least one other siliconization material; and, curing the coating mixture on the surface of the needle to provide a silicone coating thereon as required by applicants' amended claims 1 and 30.

Rather, Prasad discloses aqueous silicone coatings for use in coating surgical needles, "without the substantial use of organic solvent carriers." (See Prasad at page 2, lines 34-36.) In fact, Prasad utilizes a dispersing agent to disperse the siloxanes utilized in its coating throughout the aqueous mixture or carrier. (See Prasad at page 4, lines 18-19.) Thus, Prasad teaches away from the presently claimed coating mixture.

Moreover, as admitted in the Office Action, Prasad does not teach the viscosity of the coating composition. Thus, without any teaching or suggestion of applicants' coating mixture, i.e., a coating mixture having a viscosity of at least about 10,000 cp, Prasad fails to render the instant claims obvious and reconsideration and withdrawal of this rejection is respectfully requested.

It is believed that the claims of the application as now presented, i.e., claims 1, 3-15 and 30, are patentably distinct over the art of record and are in condition for allowance. In the event that the Examiner believes that a telephone conference or a personal interview may facilitate resolution of any remaining matters, the undersigned may be contacted at the number indicated below. In view of the foregoing amendment

Appl. No. 09/964,901  
Amdt. Dated March 3, 2005  
Reply to Office Action of November 16, 2004

and remarks, early and favorable reconsideration of this application is respectfully requested.

Respectfully submitted,



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